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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/590,834 | 08/24/2006 | Dijia Huang | 47082-117USPX | 1439 |
| 71331 | 7590 | 03/25/2010 | EXAMINER | |
| NIXON PEABODY LLP | | | DIETERLE, JENNIFER M | |
| 300 S. Riverside Plaza, 16th Floor | | | ART UNIT | PAPER NUMBER |
| CHICAGO, IL. 60606-6613 | | | 1795 | |
| MAIL DATE | | DELIVERY MODE | | |
| 03/25/2010 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|-------------------------------------|
| Office Action Summary | Application No. 10/590,834 | Applicant(s) HUANG ET AL. |
| | Examiner Jennifer Dieterle | Art Unit 1795 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 May 2009.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10 and 17-24 is/are pending in the application.
- 4a) Of the above claim(s) 11-16 and 25-30 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10 and 17-24 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/06)
 Paper No(s)/Mail Date 11/15/07, 7/18/08
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date: _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Status of the Claims

Claims 11-16 and 25-30 have been restricted.

Claims 1-10 and 17-24 are being examined.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- Group I, claims 1-10 and 17-24, drawn to an electrochemical sensor for detecting the concentration of an analyte.
- Group II, claims 11-16 and 25-30, drawn to a method for evaluating whether an electrochemical sensor is properly filled.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups I and II share the feature of a working and a counter electrode, the counter electrode having a high and low resistance portion. EP 1 074 832 A1 (provided in applicant's prior art of record) discloses a working and a counter electrode, the counter electrode having a high and low resistance portion. Therefore, the common feature between the two groups, an impedance element, does not provide a contribution over the prior art, and, thus, cannot

be a special technical feature. Therefore, Groups I and II do not relate to a single inventive concept under PCT Rule 13.1.

During a telephone conversation with David McKone on March 2, 2010, a provisional election was made without traverse to prosecute the invention of Group 1, claims 1-10 and 17-24. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11-16 and 25-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Double Patenting

2. Claims 1, 2, 5-10, 17, 18 and 20-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,841,052. With regard to claims 1, 2, 5-10, 17, 18 and 20-24, although the conflicting claims are not identical, they are not patentably distinct from each other because both provide for an electrochemical sensor for the detection of glucose comprising a working electrode and a counter having both a low and high resistance portion located downstream and upstream respectively, from the working electrode.

3. Claims 3, 4 and 19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,841,052 in view of Bhullar et al. (US 6,814,844 B2). With regard to claims 3, 4 and 19 although the conflicting claims are not identical, they are not patentably distinct from each other because both provide for an electrochemical sensor for the detection of glucose comprising a working electrode and a counter having both a low and high resistance portion located downstream and upstream respectively, from the working electrode. However, Patent No. 6,841,052 does not contain a resistor. Bhullar et al. (US 6,814,844 B2) teach the use of resistive screen-printed carbon layer that can be incorporated into the sensor aid in the contrasting of electrical properties (see col. 3-4). Therefore, it would have been obvious to one skilled in the art to modify the counter electrode by incorporating a screen-printed carbon pattern (i.e. resistor) as taught by Bhullar et al. because the carbon layer will act as a resistor and direct current/limit current flow to particular parts of the circuit and in contrasting the electrical conductivity when one or both of the high and low resistance portions of the counter electrode are covered in fluid.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

Art Unit: 1795

regards as the invention. Claim 17 refers to a "low-resistance counter electrode" and a "high-resistance counter electrode" from which it appears that applicant is claiming two separate counter electrodes; however, applicant's specification (see for example sections 0006, 0007 and 0022 and figures 2a-c) only teach the use of one counter electrode. This counter electrode has two sections, a "low-resistance section" and a "high-resistance section." This claim should be rewritten to more clearly communicate that there is only one counter electrode, but that the counter electrode can have a "low-resistance section" and a "high-resistance section."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 5-10, 17, 18 and 20-24 are rejected under 35 U.S.C. 102(b) as anticipated by Musho et al. (EP 1 074 832 A1).

Regarding claims 1 and 17, Musho et al. teach an electrochemical sensor comprising (abstract, section [0008]):

- A flow path for a blood sample (section [0008]);
- A detector to which leads are coupled;
- A working electrode;
- A reference (i.e. counter) electrode; and

- A reagent located on the working electrode (i.e. glucose oxidase (col. 9, lines 30-35).

Given that there is a detector that detects signals from the working and reference electrodes, it would be inherent that there are first and second leads connecting the electrodes to the detector. The sensor of Musho et al. is adapted to detect under fill situations and generate an error signal based on the communication of the analyte and the low and high resistance portion of the counter electrode (col. 7).

Regarding the reference electrode, Musho et al. teach that the reference electrode has a major portion located downstream 40 from the working electrode 39 and a small portion located upstream 40a of the working electrode (abstract, figure 1). In viewing Musho et al. figure 1, the upstream portion of the reference electrode 40a is smaller than the downstream portion of the reference electrode 40 from which the upstream portion 40a will have a higher resistance than the portion located downstream (see figure 1).

Additionally, With respect to 40 being a reference electrode, the terms "reference" and "counter" merely specify the intended use of the electrode and do not infer any structural distinction to the electrodes. Hence electrode 40 would read on the claimed counter electrode.

With respect to the production of first and second current profiles, these limitations do not further define the structure of the electrochemical sensor, but only specify how the electrochemical sensor is intended to be operated. Hence, these limitations do not further define the actual structure of the sensor, but merely set forth

the intended use of the sensor. Intended use need not be given further due consideration in determining patentability of an apparatus.

Regarding claims 2, 7, 18 and 22, these claims relate to the production of the current profiles discussed in claims 1 and 17 above. Since it is the intended use of the sensor to produce these current profiles, intended use need not be given further due consideration in determining patentability of an apparatus.

Regarding claims 5 and 20, Musho et al. teach an electrochemical sensor comprising a working electrode 39 and an upstream, high-resistance counter electrode wherein when an inadequate amount of blood enters the sensor, electrical connection between the upstream, high-resistance counter electrode and the working electrode will be very weak and the detector will give an error signal due to inadequate fill (sections [0008], [0012] and [0014]).

Regarding claims 6 and 21, Musho et al. teach an electrochemical sensor comprising a working electrode 39 and a downstream, low-resistance counter electrode wherein when a full amount of blood enters the sensor, the detector will sense a current that is stronger than when the downstream counter electrode is not completely covered, thus indicating proper fill (sections [0008], [0012] and [0014]).

Regarding claims 8 and 23, Musho et al. is adapted to detect under fill situations and generate an error signal and that the signal is due to current/voltage wherein the leads of the sensor are connected to a detector (col. 7).

Regarding claims 9 and 24, Musho et al. teach a reagent located on the working electrode (i.e. glucose oxidase; col. 9, lines 30-35).

Regarding claim 10, Musho et al. teach an electrochemical sensor comprising a reaction layer 44 covering the working electrode 39a and the downstream, low-resistance counter electrode 40 (sections [0012-13], see figures 1 and 2 illustrating the covering).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 1795

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 3, 4 and 19 are rejected under 35 U.S.C. 103(a) as obvious over Musho et al. (EP 1 074 832 A1) in view of Bhullar et al. (US 6,814,844 B2).

Regarding claims 3, 4 and 19, Musho et al. teach an electrochemical sensor, but does not teach the use of a screen-printed resistor between the high and low resistance portion of the counter electrode.

Bhullar et al. teach an electrochemical sensor in which a discernible code pattern 40 is formed from the electrical conductor 13 by removing the electrical conductor 13 in a pre-defined pattern to expose the first surface 22 of the support substrate 12. Next, Bhullar et al. utilizes structures that can show a contrast in their electrical conductivity or their resistivity. To aid in contrasting the electrical conductivity of the code pattern 40, the electrical conductor 13 may be coated with a second conductive material (not shown) that is different from the electrical conductor. Screen-printed carbon can be

utilized in order to limit current/direct current flow. Since the known properties of carbon provide it with a resistivity ranging from 1 ohm to 10 megohm, carbon can be construed as a "resistor" in the sense that it is utilized to direct current/limit current flow to particular parts of the circuit (col. 3-4).

Therefore, it would have been obvious to one skilled in the art to modify the counter electrode of Musho et al. by incorporating a screen-printed carbon pattern (i.e. resistor) as taught by Bhullar et al. because the carbon layer will act as a resistor and direct current/limit current flow to particular parts of the circuit and in contrasting the electrical conductivity when one or both of the high and low resistance portions of the counter electrode are covered in fluid.

7. Claims 1, 2, 5-10, 17, 18 and 20-24 are rejected under 35 U.S.C. 103(a) as obvious over Musho et al. (EP 1 074 832 A1) in view of Genshaw et al. (US 5,620,579).

Regarding claims 1 and 17, Musho et al. teach an electrochemical sensor as described at numeral 4 above. Additionally, Musho et al. teach a "read to burn" ratio (col. 8) which characterizes the magnitude of initial current in relation to the final current which represents a decay-type shape (i.e. applicant's claimed second current profile). If a decay-type shape is not obtained, the profile would have a similar shape between the voltage and current profiles indicating that the full reaction has not taken place and that there is something wrong in the sensor (see col. 7 teaching under fill situations).

While Musho et al. teach the detection of under filling of the sensor through the use of the counter electrode, Musho et al. does not specifically teach a first and second current profile.

Genshaw et al. teach an electrochemical sensor having a similar structure to that of Musho et al. Genshaw et al. teach a "read-to-burn" ratio in figures 1a and 1b. In figure 1a, represents a decay curve or can be construed as the "second" current profile when the sensor is filled properly and communication occurs between both portions of the counter electrode. Additionally, figure 1b can be construed as the "first" current profile wherein a voltage is applied and a reading obtained. If the obtained "first" current profile is abnormal, that is a *decay type profile* is not obtained and the read and burn profiles are similar, this is a known indication of a malfunction in the sensor, such as an under fill situation, and a new measurement can be obtained. Both figures 1a and 1b can be compared (see col. 4-6).

Therefore, it would have been obvious to one skilled in the art to modify the sensor of Musho et al. to obtain first and second current profiles and compare these profiles as taught by Genshaw et al. because the comparison of current profiles will show abnormalities in sensor function and can indicate situation such as under filling, bias, etc. and the test can be repeated to obtain accurate analyte concentration.

Regarding claims 2 and 18, Musho et al. in view of Genshaw et al. teach that read-to-burn current profiles can be obtained for a sensor with a proper fill and that they will be decay type shape as noted for claims 1 and 17 above.

Regarding claims 5 and 20, Musho et al. teach an electrochemical sensor comprising a working electrode 39 and an upstream, high-resistance counter electrode wherein when an inadequate amount of blood enters the sensor, electrical connection between the upstream, high-resistance counter electrode and the working electrode will be very weak and the detector will give an error signal due to inadequate fill (sections [0008], [0012] and [0014]).

Regarding claims 6 and 21, Musho et al. teach an electrochemical sensor comprising a working electrode 39 and a downstream, low-resistance counter electrode wherein when a full amount of blood enters the sensor, the detector will sense a current that is stronger than when the downstream counter electrode is not completely covered, thus indicating proper fill (sections [0008], [0012] and [0014]).

Regarding claims 7 and 22, Musho et al. in view of Grenshaw et al. teach read-to-burn current profiles wherein a decay-type profile does not occur when electrical communication occurs between the high-resistance counter electrode and the working electrode (see figures 1a and 1b).

Regarding claims 8 and 23, Musho et al. is adapted to detect under fill situations and generate an error signal and that the signal is due to current/voltage wherein the leads of the sensor are connected to a detector (col. 7).

Regarding claims 9 and 24, Musho et al. teach a reagent located on the working electrode (i.e. glucose oxidase; col. 9, lines 30-35).

Regarding claim 10, Musho et al. teach an electrochemical sensor comprising a reaction layer 44 covering the working electrode 39a and the downstream, low-resistance counter electrode 40 (sections [0012-13], see figures 1 and 2 illustrating the covering).

8. Claims 3, 4 and 19 are rejected under 35 U.S.C. 103(a) as obvious over Musho et al. (EP 1 074 832 A1) and Genshaw et al. (US 5,620,579) in view of Bhullar et al. (US 6,814,844 B2).

Regarding claims 3, 4 and 19, Musho et al. teach an electrochemical sensor, but does not teach the use of a screen-printed resistor between the high and low resistance portion of the counter electrode.

Bhullar et al. teach an electrochemical sensor in which a discernible code pattern 40 is formed from the electrical conductor 13 by removing the electrical conductor 13 in a pre-defined pattern to expose the first surface 22 of the support substrate 12. Next, Bhullar et al. utilizes structures that can show a contrast in their electrical conductivity or their resistivity. To aid in contrasting the electrical conductivity of the code pattern 40, the electrical conductor 13 may be coated with a second conductive material (not shown) that is different from the electrical conductor. Screen-printed carbon can be

utilized in order to limit current/direct current flow. Since the known properties of carbon provide it with a resistivity ranging from 1 ohm to 10 megohm, carbon can be construed as a "resistor" in the sense that it is utilized to direct current/limit current flow to particular parts of the circuit (col. 3-4).

Therefore, it would have been obvious to one skilled in the art to modify the counter electrode of Musho et al. by incorporating a screen-printed carbon pattern (i.e. resistor) as taught by Bhullar et al. because the carbon layer will act as a resistor and direct current/limit current flow to particular parts of the circuit and in contrasting the electrical conductivity when one or both of the high and low resistance portions of the counter electrode are covered in fluid.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dieterle whose telephone number is (571) 270-7872. The examiner can normally be reached on Monday thru Friday, 8am to 5pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1795

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/
Supervisory Patent Examiner, Art Unit 1753

JMD
3/10/10